# APPLICATION FORMS AND INSTRUCTIONS FOR THE MEDICARE REPLACEMENT DRUG DEMONSTRATION

As part of the Medicare Modernization and Improvement Act of 2003 (MMA) you may be eligible to participate in a time-limited opportunity to have certain drugs covered by Medicare before Medicare's prescription drug program begins in 2006. To apply you must be currently eligible for Medicare Part A coverage, be enrolled in Medicare Part B, and live in one of the 50 United States or the District of Columbia. In addition, Medicare must be your primary insurer and you must have been diagnosed by a physician with a condition that is treated with one of the covered prescription drugs. If you do not meet these criteria you should not submit an application.

Under the Medicare Replacement Drug Demonstration people who have been diagnosed with rheumatoid arthritis, multiple sclerosis, osteoporosis, pulmonary hypertension, secondary hyperparathyroidism, Paget's Disease, Hepatitis C, CMV retinitis, or certain kinds of cancer may be eligible to have Medicare pay for certain self-administered drugs and biologicals that replace the need for drugs that are currently covered under Medicare Part B but are generally only available when provided in the doctor's office.

If you think you might be eligible to participate in this demonstration you should complete the application and have your physician complete the physician certification form and mail or fax it to the address below. It must be received by Thursday, September 30, 2004, in order to receive full consideration. Submitting an application is the only way you can be considered for participation.

Under the law, this demonstration is limited to no more than 50,000 participants and \$500 million in spending. If more people apply than we can serve, participants will be randomly selected. All applications received by September 30, 2004, will have an equal chance of being chosen to participate in this demonstration.

If you are a Medicare recipient who has limited income and financial resources and cannot afford the drugs you need for any of the conditions listed above, you may qualify for additional coverage. In this case you should also complete the Financial Assistance Application form and mail it to the address below with your application. If you do not think you qualify for financial assistance you do not need to return the Financial Assistance Application form. However, your application will be considered without regard to whether you are applying for financial assistance.

If you have any questions about the Medicare Replacement Drug Demonstration or if you need assistance in completing the application please contact:

Medicare Replacement Drug Demonstration c/o TrailBlazer Health Enterprises, L.L.C. P.O. Box 5136 Timonium, MD 21094 1-866-563-5386 TTY 1-866-563-5387 FAX 410-683-2933 www.medicare.gov

#### **ENROLLMENT FORM FOR MEDICARE REPLACEMENT DRUG DEMONSTRATION**

SECTION I							
First Name	Middle Initial	Last Name		Date of I	Birth (month/d	lay/year)	Sex
Residence Street A	Address			City		State	ZIP Code
Medicare ID Numb	er		Telephone N	lumber (w	ith area code)		'
SECTION II: I	Medicare Coverage	Information					
1. Do you curre	ently have Medicare Pa	art A?		☐ Yes	□ No		
2. Do you curre	ently have Medicare Pa	art B?		☐ Yes	□ No		
State Medica	ive assistance from you aid Program in paying ium or out-of-pocket co	for your Medica	re	☐ Yes	□ No		
•	other health insurance at provides coverage for		gs?	☐ Yes	□ No		
		swered Yes to Q pelow, "Other H				<b>,</b> ,	
SECTION III:	Other Health Insura	ance Informati	on				
1. What other h	nealth insurance do you	a have that cover	rs outpatient	drugs (	check all the	nat appl	y)?
☐ Medicaid			☐ TriCare				Veteran's benefit
	ouse's employer health	•	☐ Privately-	•			edi-gap)
	ounty program other th	an Medicaid	☐ Pharmacy	compar	ny progran	1	
☐ Other: (pl	ease describe)						
☐ Yes ☐	nnual dollar coverage leads No the specify the dollar lim	Ť					
☐ Yes ☐	onthly limit to the num No		·		·		
If Yes, please	e specify the number o	f prescriptions a	llowed per n	nonth? <sub>-</sub>			

	ECTION IV: Medication Information ote: You must complete this page for EACH medication you are requesting. If you are requesting more than one medication, please photocopy this page before completing.)
1.	What medication are you seeking coverage for under the demonstration?
2.	Are you currently taking this medication? ☐ Yes ☐ No
3.	What disease or condition do you/will you take this medication for?
	YOUR DOCTOR MUST ALSO SUBMIT A SIGNED CONFIRMATION OF THIS DIAGNOSIS BEFORE YOU CAN BE ENROLLED IN THIS DEMONSTRATION. PLEASE USE THE FORM PROVIDED FOR THIS PURPOSE.
	If you are currently taking this medication, how have you been paying for it?  ☐ I pay for it all myself.
	☐ I pay for most of it myself, but some costs have been covered through insurance or a drug assistance plan.
	☐ Most of the costs are paid by insurance or a drug assistance plan. I pay only a little or nothing at all.
	If you are NOT currently taking this medication and have other health insurance coverage (See Section III previous page), will this coverage pay for the drug for which you are seeking coverage under this demonstration?
	☐ No, because I've already used up the annual dollar limit: \$
	☐ No, because I've already filled the number of prescriptions allowed each month.
	☐ No, because this drug is not covered under my current drug plan.
	<ul><li>☐ Yes, it would pay some of the costs but less than this coverage.</li><li>☐ I don't have other insurance.</li></ul>
	If you are NOT currently taking the medication listed in question 1, are you taking another medication to treat this condition that you will stop taking if you enroll in this demonstration?  Yes □ No
	If Yes, what is the name of this medication?
7.	How have you been paying for this medication?
	☐ I pay for it all myself.
	☐ Medicare pays for some of it and I pay some.
	☐ Medicare pays for some and my supplemental health plan pays for the rest.
	☐ I have a supplemental drug plan that pays some but I pay for most of it myself.
	☐ I have a supplemental drug plan that pays for all or almost all of it.

SECTION V: PROXY INFORMATION	
If this form is being completed on behalf of a Me	edicare beneficiary, please provide the following information:
Name	
Relationship to Beneficiary	Phone Number ()
Signature of Proxy	Date
PLEASE READ ALL OF THE INFOR	RMATION BELOW AND SIGN AT THE BOTTOM
YOUR APPLICATION IS NOT COM	PLETE WITHOUT THIS FORM BEING SIGNED
Medicare & Medicaid Services (CMS) to give in	ollment in this demonstration, I allow the Centers for formation to any organizations administering this benefit on I am selected to participate in this demonstration, I may be of CMS to evaluate this demonstration.
	olication does not guarantee coverage under the demonstration demonstration, coverage may be limited to the terms and
national origin, or political belief. I agree to provide	ed without regard to race, color, sex, age, handicap, religion, de any documents necessary to confirm the accuracy and application. If documents are not available, I agree to give rovide and release this necessary information.
cannot sign, a representative may sign for you.) I	nderstand the information on this enrollment form. (If you Federal law provides for a fine or imprisonment, or both, for tion to obtain assistance to which (s)he is not entitled.
I understand the questions on this application and by me on this form is correct and complete to the	I I certify, under penalty of perjury, that the information given best of my knowledge.
Signature of Beneficiary	Date
OR	
Signature of Person Completing this Form	Date

Return completed application to: Medicare Replacement Drug Demonstration, c/o TrailBlazer Health Enterprises, L.L.C., P.O. Box 5136, Timonium, MD 21094 or fax to: 410-683-2933

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0924 (Expiration Date 12/31/2004). The time required to complete this information collection is estimated to average 15 minutes per response, including the time to reviewinstructions, search existing data resources, gather the data needed, and complete and reviewthe information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

# PART II: MEDICAL CERTIFICATION OF BENEFICIARY ELIGIBILITY FOR MEDICARE REPLACEMENT DRUG DEMONSTRATION

Dear Prescribing Clinician:

Your patient has applied to participate in a Medicare demonstration that will provide coverage for certain self-administrable drugs and biologicals that are replacements for drugs that are covered under Medicare Part B. Eligibility for this demonstration, is not contingent upon whether the beneficiary is currently taking any specific drug, but only that the beneficiary has a condition for which you have prescribed, or plan to prescribe if your patient is selected to participate in this demonstration, a drug that is covered under the demonstration for that condition. Some of the questions below are for the purposes of collecting descriptive information only about beneficiaries who are applying for this demonstration in order to support a Report to Congress that is mandated under the law. All beneficiary specific information will be kept strictly confidential.

The list of drugs and conditions covered under the demonstration is attached. If accepted to participate in this demonstration, the beneficiary will receive assistance from Medicare to help pay for these medications. The beneficiary may be required to pay certain deductibles or coinsurance although assistance for low-income beneficiaries is available. For more information about this demonstration, please contact 1-866-563-5386 (TTY 1-866-563-5387) or visit our web site at <a href="http://www.cms.hhs.gov/researchers/demos/drugcoveragedemo.asp">http://www.cms.hhs.gov/researchers/demos/drugcoveragedemo.asp</a>.

By signing below, you are certifying that this patient has the condition indicated and that you have prescribed or intend to prescribe this drug for this condition in accordance with demonstration requirements. Your signed certification is necessary for the beneficiary's application to participate in this demonstration to be complete. Incomplete applications will not be considered. Due to limited funds and enrollment capacity, completion of an application is not a guarantee of coverage under the demonstration.

Completed applications should be returned to: Medicare Replacement Drug Demonstration, c/o TrailBlazer Health Enterprises, L.L.C., P.O. Box 5136, Timonium, MD 21094 or fax to: 410-683-2933.

ast Name	First Name	Middle Name	Patient's Phone	Medicare ID#
Pate of Birth (mm/dd/yyy	y) Drug Prescribe	ed / To be Prescribed		NDC Code (if available)
Condition Treated (ICD9	Code – if available)	Disease Stage	e (if applicable)	Is Patient Homebound
				□ Yes □ No
D.No. This	cription does not real	ana a Madiana Dant D	1 11 11	
or has takens or would this I Yes, this is a n	ken. be a new prescription	?	covered medication	on this patient is taking
or has takes or would this Yes, this is a n	ken. be a new prescription new prescription.	? medication	covered medication	on this patient is taking
or has takes this or would this  Yes, this is a number No, patient is	ten.  be a new prescription new prescription.  currently taking this r	? medication	DEA #	Phone

Form CMS-10113B (08/04) EF 08/2004

## DRUGS COVERED UNDER THE MEDICARE REPLACEMENT DRUG DEMONSTRATION

Demonstration Covered Indication	Drug/Biological—Compound Name (Brand Name)
Rheumatoid Arthritis	Adalimumab (Humira)
	Anakinra (Kineret)
	Etanercept (Enbrel)
Multiple Sclerosis	Glatiramer acetate (Copaxone)
	Interferon beta –1a (Rebif, Avonex)
	Interferon beta –1b (Betaseron)
Osteoporosis (patient must be homebound)	Calcitonin – nasal (Miacalcin – nasal)
Pulmonary Hypertension	Bosentan (Tracleer)
Secondary Hyperparathyroidism	Doxercalciferol (Hectoral)
Paget's Disease	Alendronate (Fosamax)
	Risedronate (Actonel)
Hepatitis C	Pegylated interferon alfa-2a (Pegasys)
	Pegylated interferon alfa-2b (PEG-Intron)
CMV Retinitis	Valcyte (Valganciclovir)
Acromegaly	Pegvisomant (Somavert)
Anti-Cancer	
Cutaneous T-cell Lymphoma	Bexarotene (Targretin)
Non-small cell lung cancer	Gefitinib (Iressa)
Epithelial ovarian cancer	Altretamine (Hexalen)
Chronic Myelogenous Leukemia	Imatinib Mesylate (Gleevec)
GI Stromal Tumor	Imatinib Mesylate (Gleevec)
Multiple Myeloma	Thalidomide (Thalomid)
Breast Cancer	Hormonal therapy
Stage 2-4 only	Anastrozole (Arimidex)
	Exemestane (Aromasin)
	Letrozole (Femara)
	Tamoxifen (Nolvadex)
	Toremifene (Fareston)
Prophylactic agent to reduce ifosfamide-induced	Mesna-oral tablets (Mesnex)
hemorrhagic cystitis	

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## MEDICARE REPLACEMENT DRUG DEMONSTRATION FINANCIAL ASSISTANCE APPLICATION

If your annual income is less than 150% of the Federal poverty level and you have other financial resources worth less than \$10,000, for an individual, (\$20,000 for a couple), you may qualify for financial assistance under this demonstration.

There are five different benefit categories under this demonstration. There is a standard benefit level and, for those with limited incomes and financial resources, four different levels of benefit subsidy corresponding to different income levels. Each benefit category has a different type of cost sharing as shown in Table 1. Table 2 shows which benefit category you are eligible for, depending upon your annual income and financial resources.

If you are receiving assistance from your State Medicaid program in paying for your Medicare Part B premiums or out-of-pocket costs, you may be eligible for coverage under Benefit Level 3.

In order for us to determine whether you qualify for any of these enhanced benefit levels, please provide us with the information requested on this form about your annual income and other financial resources. Your signature at the bottom of the form will attest that this information is true and accurate to the best of your knowledge.

If you do not believe that you qualify for low-income assistance or do not wish to complete this form, you may still be eligible to enroll in this demonstration and receive the standard benefit package. Just complete the regular enrollment application and send it to the address indicated.

For more information, please contact 1-866-563-5386 (TTY 1-866-563-5387).

# TABLE 1: MEDICARE REPLACEMENT DRUG DEMONSTRATION

# Benefit Categories IABLE

	Benefit Level 1 (Standard)	Benefit Level 2 <sup>2</sup>	Benefit Level 3	Benefit Level 4	Benefit Level 5
Annual Deductible	• In 2004: \$85 • In 2005: \$250	• In 2004: \$20	0\$	0\$	\$0
After the annual deductible, you pay this amount for each prescription until you have reached the specified out-ofpocket limit <sup>11</sup>	<ul> <li>1n 2004:</li> <li>25% coinsurance until you have paid \$165 in additional out-of-pocket costs and then,</li> <li>100% of all costs until you have reached the out-of-pocket limit of \$1,200 (i.e., the next \$950 in allowable costs out of pocket)</li> <li>1n 2005:</li> <li>25% coinsurance until you have paid \$500 in additional out-of-pocket costs and then,</li> <li>100% of all costs until you have reached the out-of-pocket limit of \$3,600 (i.e., the next \$2,850 in allowable costs out of pocket</li> </ul>	• 15% coinsurance	• A fixed co-payment of \$2 for generic or preferred multibrand drugs or \$5 for all other drugs	• A fixed co-payment of \$1 for generic or preferred multibrand drugs or \$3 for all other drugs	You pay nothing
Once you have paid \$3,600 (\$1,200 in 2004) in total out of pocket costs, you pay this amount for each prescription	Once you have paid \$3,600 (\$1,200 in 2004) in total out of pocket costs, you pay this amount for each prescription  The greater of:  • 5% or  • A fixed co-payment of \$2 for generic or preferred multi-brand drugs or \$5 for all other drugs	You pay:  • A fixed co-payment of \$2 for generic or preferred multibrand drugs or \$5 for all other drugs	You pay:  • A fixed co-payment of \$2 for generic or preferred ferred multi-brand drugs or \$5 for all other drugs	You pay nothing	You pay nothing

<sup>&</sup>lt;sup>1</sup>Any amount paid by other insurance, with the exception of a State pharmacy assistance program or certain charitable organizations may NOT be counted toward your out of pocket limit.

For Benefit Level 2, out of pocket payments from both Medicare and the beneficiary count towards \$3,600 catastrophic limit (\$1,200 in 2004).

Form CMS-10113C (07/04)

TABLE 2: ARE YOU ELIGIBLE FOR FINANCIAL ASSISTANCE?

Total Financial Resources are  And Your income is:	Less than:  • \$6,000 for an individual, or  • \$9,000 for a couple	Between  • \$6,000 and  \$10,000 for an individual, or  • \$9,000 and  \$20,000 for a couple	Over  • \$10,000 for an individual, or  • \$20,000 for a couple
Less than 100% of the Federal Poverty Level (FPL) and you are a full benefit dual Medicare and Medicaid eligible beneficiary (1)(2)	Benefit Level 4	Benefit Level 4	Benefit Level 4
100% or more than the FPL and you are a full benefit dual Medicare and Medicaid eligible beneficiary (1)(2)	Benefit Level 3	Benefit Level 3	Benefit Level 3
Less than 135% of the FPL and you are not a full benefit dual Medicare and Medicaid eligible beneficiary	Benefit Level 3	Benefit Level 2	Benefit Level 1
135% or more of the FPL but less than 150% of the FPL and you are not a full benefit dual Medicare and Medicaid eligible beneficiary	Benefit Level 2	Benefit Level 2	Benefit Level 1
150% or more of the FPL and you are not a full benefit dual Medicare and Medicaid eligible beneficiary	Benefit Level 1	Benefit Level 1	Benefit Level 1

#### Notes:

- (1) Institutionalized full benefit dual Medicare and Medicaid eligible beneficiaries will be covered under Benefit Level 5 (See Table 2).
- (2) Most full benefit dual Medicare and Medicaid eligible beneficiaries receive a comprehensive drug benefit through the Medicaid program. Only beneficiaries who do not already have a comprehensive drug benefit through their Medicaid program are eligible to participate in this demonstration.

#### **FEDERAL POVERTY LEVEL GUIDELINES FOR 2004**

	100 % of Federal Poverty Level		135% of Federal Poverty Level		150% of Federal Poverty Level	
	Individual	Couple	Individual	Couple	Individual	Couple
Lower 48 States	\$9,310	\$12,490	\$12,569	\$16,862	\$13,965	\$18,735
Alaska	\$11,630	\$15,610	\$15,701	\$21,074	\$17,445	\$23,415
Hawaii	\$10,700	\$14,360	\$14,445	\$19,386	\$16,050	\$21,540

# MEDICARE REPLACEMENT DRUG DEMONSTRATION ATTESTATION OF INCOME AND FINANCIAL RESOURCES

Determination of eligibility for this demonstration follows income and financial resource guidelines established by the Social Security Administration. Certain income and resources may be excluded when reporting income and resources. For a complete list of what should be included and excluded, please refer to the attached guidelines or check the following web site: <a href="http://www.ssa.gov/oact/ssir/ssi03/exclusions.html">http://www.ssa.gov/oact/ssir/ssi03/exclusions.html</a> or contact your local Social Security Office.

First Name	Middle Initial	Last Name	Social Security Number
Residence Street Address		City	State ZIP Code
Phone Number		<u> </u>	Marital Status  ☐ Single ☐ Married
If married, please prov	vide the following information	on about your spouse.	<u>.</u>
Spouse's First Name	Middle Initial	Last Name	Social Security Number
☐ Private Reside	nce or an institution such as ance I Number	rsing Home	
	I Income (If married, includ	de both your income and sp	vouse's income)
SECTION II: Annua			
SECTION II: Annua 1. What is your annua	l earned income?	<b></b>	
1. What is your annua	l earned income? ————————————————————————————————————	ent.	

Include income from such sources as Social Security, Railroad Retirement or other pension/retirement benefits, veterans' benefits, trust or annuity payments, interest, rental income, dividends, royalties, etc.

# 1. Do you, or your spouse, own or co-own any of the following: savings accounts, checking accounts, government bonds, trust funds, savings bonds, stocks or bonds, certificates of deposit, IRAs, life insurance policies, recreational vehicles, etc?

**Section III: Resources** (If married, include resources belonging to both you and your spouse.)

position, recreational venteres, etc.	_ 10	
If YES, what is the cash value of these items?	-	
2. Do you, or your spouse, own all or part of any real estate in	n which you do NOT live? ☐ Ye	s 🖵 No
If YES, what is the value of this real estate after excluding any outstanding loans?	-	

3. Do you, or your spouse, own or co-own more than one vehicle for transportation?	☐ Yes	□N
--	-------	----

If YES, what is the cash value of these items	
after excluding any outstanding loans?	

# PLEASE READ ALL OF THE INFORMATION BELOW AND SIGN AT THE BOTTOM YOUR APPLICATION IS NOT COMPLETE WITHOUT THIS FORM BEING SIGNED

**Release of Information:** By applying for enrollment in this demonstration, I allow the Centers for Medicare & Medicaid Services (CMS) to give information to any organizations administering this benefit on my behalf. I also understand that, whether or not I am selected to participate in this demonstration, I may be contacted by an organization working on behalf of CMS to evaluate this demonstration.

**Review of Eligibility:** I understand that my application does not guarantee coverage under the demonstration and that should I be selected to participate in the demonstration, coverage may be limited to the terms and conditions of the demonstration.

I understand that my application will be considered without regard to race, color, sex, age, handicap, religion, national origin, or political belief. I agree to provide any documents necessary to confirm the accuracy and completeness of the information provided in this application. If documents are not available, I agree to give the name of the person or organization that can provide and release this necessary information.

By signing below, I certify that I have read and understand the information on this enrollment form. (If you cannot sign, a representative may sign for you.) Federal law provides for a fine or imprisonment, or both, for any person who withholds or gives false information to obtain assistance to which (s)he is not entitled.

I understand the questions on this application and I certify, under penalty of perjury, that the information given by me on this form is correct and complete to the best of my knowledge.

Signature of Beneficiary	Date
OR	
Signature of Person	
Completing this Form	Date
Relationship	
to Beneficiary	Phone Number
Completed forms should be returned to: Medicare Replacement Drug Demonstration c/o TrailBlazer Health Enterprises, L.L.C.	
	P.O. Box 5136
	Timonium, MD 21094

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FAX 410-683-2933

OR

#### INCOME AND RESOURCE EXCLUSIONS

#### 1. Earned Income Exclusions

- Any refund of Federal income taxes received under section 32 of the Internal Revenue Code (relating to **earned income tax credit**) and any payment received under section 3507 of the Internal Revenue Code (relating to advance payment of earned income tax credit);
- Any refundable child tax credit (which increases gradually from the current amount of \$600 for each child to \$1,000 per child in 2010);
- Up to \$10 of earned income in a month if it is **infrequent or irregular**, that is, if it is received only once in a calendar quarter from a single source or if its receipt cannot reasonably be expected. (If the total amount of the infrequent or irregular income exceeds \$10, this exclusion cannot be used.);
- Up to \$1,340 per month but not more than \$5,410 in a calendar year received by a blind or disabled child who is a student regularly attending school;
- Any portion of the monthly \$20 exclusion for unearned income that has not been used;
- \$65 of earned income in a month;
- Amounts used to pay **impairment-related work expenses** if a recipient is disabled (but not blind) and under age 65 or is disabled (but not blind) and receiving SSI (or disability payments under a former State plan) before age 65<sup>1</sup>;
- One-half of remaining earned income in a month;
- Earned income used to meet any expenses reasonably attributable to the earning of the income if the recipient is blind and under age 65 or if he/she received SSI as a blind person prior to age 65<sup>1</sup>;
- Any earned income received and used to fulfill an approved **plan to achieve self-support** if the recipient is blind or disabled and under age 65 or is blind or disabled and received SSI as a blind or disabled individual in the month before he/she attained age 65<sup>1</sup>;
- Any earned income deposited into either a **Temporary Assistance for Needy Families (TANF)** or "Assets for Independence Act" **individual development account (IDA)**; and
- Some Federal laws other than the Social Security Act provide for the exclusion of earned income for SSI purposes. For the most part, the income received under these laws relates to assistance received in the form of food, housing and utilities, educational and employment benefits or benefits derived from being a member of a Native American tribe. A complete list of laws which exclude earned income under SSI can be found in the Federal Regulations Appendix to Subpart K 20 CFR 416.

#### 2. Unearned Income Exclusions

- Any public agency's refund of taxes on real property or food;
- Assistance based on need which is wholly funded by a State or one of its political subdivisions. This includes State supplementation of Federal SSI benefits but does not include payments under a Federal/State grant program such as TANF;
- Any portion of a grant, scholarship or fellowship used for paying tuition, fees or other necessary educational expenses. Portions set aside for food, clothing or shelter are counted;
- Food raised by a **household** if it is consumed by that household;
- Assistance received under the Disaster Relief and Emergency Assistance Act and assistance provided under any Federal statute because of a catastrophe which the President of the United States declares to be a major disaster;

Amounts used to pay impairment-related work expenses are deducted before the one-half of earned income deduction, whereas amounts used to pay the work expenses of the blind are deducted after the one-half of earned income deduction. In effect, amounts of blind work expenses reduce SSI earned income twice as much as the same amounts of impairment-related work expenses.

- Up to \$20 of unearned income in a month if it is infrequent or irregular; that is, if a type of unearned income is received only once during a calendar quarter from a single source or if it cannot reasonably be expected;
- Any unearned income received and used to fulfill an approved plan to achieve self-support if the recipient is blind or disabled and under age 65 or is blind or disabled and received SSI as a blind or disabled individual in the month before he/she attained age 65;
- Periodic payments made by a State under a program established before July 1, 1973, and based solely on the recipient's length of residence and attainment of age 65;
- Payments for providing foster care to an ineligible child who was placed in the recipient's home by a public or private nonprofit child placement or child care agency;
- Any interest earned on excluded **burial funds** and any appreciation in the value of an excluded burial arrangement which are left to accumulate and become part of the separately identifiable burial fund;
- Certain support and maintenance assistance provided in the form of home energy assistance;
- One-third of support payments made by an absent parent if the recipient is a child;
- The first \$20 of unearned income in a month other than income in the form of in-kind support and maintenance received in the household of another and income based on need;
- The value of any assistance paid with respect to a dwelling unit under the United States Housing Act of 1937, the National Housing Act, section 101 of the Housing and Urban Development Act of 1965, title V of the Housing Act of 1949, or section 202(h) of the Housing Act of 1959;
- Any interest accrued on and left to accumulate as part of the value of an excluded burial space purchase agreement (after April 1, 1990);
- The value of any commercial transportation ticket, for travel by a recipient or his/her spouse among the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa and the Northern Mariana Islands, which is received as a gift and is not converted to cash;
- Payments received from a fund established by a State to aid victims of crime;
- Relocation assistance provided by a State or local government that is comparable to assistance provided under title II of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970;
- Hostile fire pay received from one of the uniformed services pursuant to 37 U.S.C. 310 and other kinds of additional pay received by military personnel in a combat zone;
- Interest or other earnings on a **dedicated account** excluded from resources;
- In-kind gifts not converted to cash and the first \$2,000 annually of cash gifts made by tax-exempt organizations, such as the Make-A-Wish Foundation, to, or for the benefit of, individuals under age 18 with life-threatening conditions;
- Payments made under the Ricky Ray Hemophilia Relief Fund Act of 1998;
- TANF funds made available to an SSI recipient as part of an individual development account (IDA);
- Deposits made by a participating individual or a sponsoring nonprofit organization or State or local government into an IDA under the "Assets for Independence Act" IDA demonstration project and interest earned on these deposits; and
- Unearned income excluded by other Federal laws. See Federal Regulations Appendix to Subpart K 20 CFR 416.

#### 3. Resource Exclusions

- The home (including the land appertaining thereto);
- Household goods and personal effects to the extent that their total value does not exceed \$2,000;
- An automobile may be totally excluded if: (1) it is necessary for employment; (2) it is necessary for the medical treatment of a specific or regular medical problem; (3) it is modified for the operation by or transportation of, a handicapped individual; or (4) it is necessary to perform essential daily activities. If the automobile does not meet any of the above requirements, it may be excluded to the extent that its current-market value does not exceed \$4,500;
- Property of a trade or business which is essential to the means of self-support;
- Nonbusiness property which is essential to the means of self-support;
- Resources of a blind or disabled individual which are necessary to fulfill an approved plan for achieving self-support;
- Stock in regional or village corporations held by natives of Alaska during the 20-year period in which the stock is inalienable pursuant to the Alaska Native Claims Settlement Act;
- Life insurance owned by an individual (and spouse, if any) provided that all life insurance on any person does not exceed a face value of \$1,500;
- Restricted allotted Indian lands;
- Disaster relief assistance;
- Burial spaces and certain funds up to \$1,500 for burial expenses;
- Title XVI or Title II retroactive payments (for 6 months following receipt);
- Housing assistance;
- Refunds of Federal income taxes and advances made by an employer relating to an earned income tax credit, (for the month following receipt);
- Refundable child tax credit (\$600 per child in the current year, gradually increasing to \$1,000 per child in 2010) in the month of receipt and in the following month;
- Payments received as compensation for expenses incurred or losses suffered as a result of a crime (for 9 months);
- Relocation assistance from a State or local government (for 9 months);
- Dedicated financial institution accounts for disabled children;
- In-kind gifts not converted to cash and the first \$2,000 annually of cash gifts made by tax-exempt organizations, such as the Make-A-Wish Foundation, to, or for the benefit of, individuals under age 18 with life-threatening conditions;
- Payments made under the Ricky Ray Hemophilia Relief Fund Act of 1998;
- Amounts deposited into either a TANF or "Assets for Independence Act" IDA, including matching funds and interest earned on such amounts:
- Certain **trusts** (e.g., those established by will or certain Medicaid trusts that will repay the State, upon the death of the beneficiary, for the costs of medical assistance provided to that individual); and
- Payments or benefits provided under a Federal statute other than Title XVI of the Social Security Act where exclusion is provided by such statute.

#### ADDITIONAL DISCLOSURE INFORMATION

#### **Authority to Collect Information:**

The authority for this system of records is Section 641 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173).

#### **Purpose of Collection Information:**

All of the included data is necessary to employ proper research methods and to verify eligibility criteria. The information is needed to confirm the beneficiaries' eligibility for enrollment and ongoing participation in the demonstration, as well as other survey and research information needed to pay claims, administer the demonstration project, and develop research reports on the study's findings. Information collected is critical to implementing the demonstration as mandated in the legislation.

#### **Privacy Act:**

The Privacy Act permits CMS to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such disclosure of data is known as a "routine use."

#### **Routine Uses:**

These routine uses specify circumstances, in addition to those provided by statute in the Privacy Act of 1974, under which CMS may release information from the Medicare Replacement Drug Demonstration (MRDD) without the consent of the individual to whom such information pertains. Each proposed disclosure of information under these routine uses will be evaluated to ensure that the disclosure is legally permissible, including but not limited to ensuring that the purpose of the disclosure is compatible with the purpose for which the information was collected. CMS proposes to establish the following routine use disclosures of information maintained in the system:

1. To agency contractors, or consultants that have been contracted by the agency to assist in the performance of a service related to this system of records and that need to have access to the records in order to perform the activity.

CMS contemplates disclosing information under this routine use only in situations in which CMS may enter into a contractual or similar agreement with a third party to assist in accomplishing agency business functions relating to purposes for this system of records.

CMS occasionally contracts out certain of its functions when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor whatever information is necessary for the contractor to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor from using or disclosing the information for any purpose other than that described in the contract and requires the contractor to return or destroy all information at the completion of the contract.

2. To a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional Office made at the written request of the constituent about whom the record is maintained.

Individuals sometimes request the help of a Member of Congress in resolving some issue relating to a matter before CMS. The Member of Congress then writes CMS, and CMS must be able to give sufficient information to be responsive to the inquiry.

- 3. To the Department of Justice (DOJ), court or adjudicatory body when:
  - a. the agency or any component thereof, or
  - b. any employee of the agency in his or her official capacity; or
  - c. any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee, or
  - d. the United States Government; is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation.

Whenever CMS is involved in litigation, or occasionally when another party is involved in litigation and CMS' policies or operations could be affected by the outcome of the litigation, CMS would be able to disclose information to the DOJ, court or adjudicatory body involved. A determination would be made in each instance that, under the circumstances involved, the purposes served by the use of the information in the particular litigation is compatible with a purpose for which CMS collects the information.

- 4. To an individual or organization engaged in, or assisting in: the appropriate submission of claims payments payable under the demonstration project; the screening, enrollment, communications, and research efforts related to beneficiary participation in the demonstration project (including summary analyses demonstrating the impact of the demonstration project); the inter-relationship of the demonstration claims processing system with other Medicare systems of records to beneficiary information and claims payment; and, other activities reasonably necessary to fulfill the provisions of the demonstration project and ensure appropriate use of Medicare trust fund and program funds.
- 5. To third party contacts in situations where the party to be contacted has, or is expected to have, information relating to the individual's capacity to manage his or her affairs or to his or her eligibility for, or an entitlement to, benefits under the Medicare program and,
  - a. The individual is unable to provide the information being sought (an individual is considered to be unable to provide certain types of information when any of the following conditions exists: the individual is confined to a mental institution, a court of competent jurisdiction has appointed a guardian to manage the affairs of that individual, a court of competent jurisdiction has declared the individual to be mentally incompetent, or the individual's attending physician has certified that the individual is not sufficiently mentally competent to manage his or her own affairs or to provide the information being sought, the individual cannot read or write, cannot afford the cost of obtaining the information, a language barrier exist, or the custodian of the information will not, as a matter of policy, provide it to the individual), or
  - b. The data are needed to establish the validity of evidence or to verify the accuracy of information presented by the individual, and it concerns one or more of the following: the individual's entitlement to benefits under the Medicare program, the amount of reimbursement, and in cases in which the evidence is being reviewed as a result of suspected fraud and abuse, program integrity, quality appraisal, or evaluation and measurement of activities.

Third party contacts require MRDD information in order to provide support for the individual's entitlement to benefits under the Medicare program; to establish the validity of evidence or to verify the accuracy of information presented by the individual, and assist in the monitoring of Medicare claims information of beneficiaries, including proper reimbursement of services provided.

#### **Additional Provisions Affecting Routine Use Disclosures:**

In addition, CMS policy will be to prohibit release even of non-identifiable data, except pursuant to one of the routine uses, if there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the population is so small that individuals who are familiar with the enrollees could, because of the small size, use this information to deduce the identity of the individual).

This System of Records contains Protected Health Information as defined by the Department of Health and Human Services' regulation "Standards for Privacy of Individually Identifiable Health Information" (45 CFR Parts 160 and 164, 65 Federal Register 82462 as amended by 66 Federal Register 12434). Disclosures of Protected Health Information authorized by these routine uses may only be made if, and as, permitted or required by the "Standards for Privacy of Individually Identifiable Health Information."

#### Note:

Enrollment and acceptance into MRDD is dependent on providing all application information. Beneficiaries who do not provide this information will be unable to participate in the demonstration.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0924 (Expiration Date 12/31/2004). The time required to complete this information collection is estimated to average 15 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security Boulevard. Baltimore. Maryland 21244-1850.